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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/763,415 | 05/16/2001 | Falk Fish | FISH4 | 9137 |

1444 7590 04/01/2005

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| EXAMINER | |
|---|---|
| HINES, JANA A | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1645 | |

DATE MAILED: 04/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| **Advisory Action Before the Filing of an Appeal Brief** | **Application No.** 09/763,415 | **Applicant(s)** FISH, FALK | |
|---|---|---|---|
| | **Examiner** Ja-Na Hines | **Art Unit** 1645 | |

***--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --***

THE REPLY FILED 28 December 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The reply was filed after the date of filing a Notice of Appeal, but prior to the date of filing an appeal brief. The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): The rejection of claim 9 under 35 U.S.C. 112, second paragraph.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: *1,4 and 5*.
   Claim(s) objected to: *None*.
   Claim(s) rejected: *6-10 and 12*.
   Claim(s) withdrawn from consideration: *None*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____.

K. J. Smith
Primary Examiner
Art Unit: 1645

Continuation of 11. does NOT place the application in condition for allowance because: The rejection of claim 10 under 35 U.S.C. 102(b) as being anticipated by Paisey et al., is maintained for the reasons already of record. Applicants' urge that the methods of Paisey et al., do not measure glucose levels and that one skilled in the art would not expect Paisey et al., to use the same reagents and detection methods. However, it is noted that the claims are not drawn to a method of detection nor are the claims drawn to methods using said reagents. Rather, the claims are drawn to a kit which comprises a hair removal means; a diluent; a means for measuring the level of blood component and glucose; and a means for calculation. Paisey et al., teach means which meet the limitations of the claims. Moreover, the means taught by Paisey et al., are capable of performing the intended use of the claimed means, thus Paisey et al., meets the limitation of the claims. Since there are structural differences between the claimed means and the prior art means which would distinguish the claimed invention from the prior art and applicant has failed to point out the structural differences, the rejection of the claims is maintained. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies i.e., measuring the level of glucose in the sample selected from the group consisting of fluorescence, chemiluminescence, bioluminescence, colorimetric method and electrochemical methods are not recited in the rejected claims.

The rejection of claims 6-8 and 12-13 under 35 U.S.C. 103(a) as being unpatentable over Paisey et al., in view of Sigma Chemical Company Catalog 1992 is maintained for reasons already of record. The rejection is not presaussive since it would have been prima facie obvious at the time of applicants invention to modify the kit that includes a means for obtaining a hair sample; a means for measuring the level of blood components; a separation means; a means for measuring the level of blood component and glucose; and a means for calculation wherein the modification comprises using an alternative and functionally equivalent measuring means and a lysis reagent. In this case, one would have a reasonable expectation of success by incorporating the lysis reagent and colorimetric determination method since it was already known in the art to lyse blood cells in order to release their contents and allow the accessible contents such as glucose to be colorimetrically measured. Thus the rejection is maintained.

The rejection of claim 9 under 35 U.S.C. 103(a) as being unpatentable over Paisey et al., in view of Albarella et al., (US Patent 4,017,261) is maintained for reasons already of record. Applicants assert that Albarella et al., adds nothing to Paisey et al. However it is the examiner's position that in this case, one would have a reasonable expectation of success by incorporating the test strip since it was already known in the art to colorimetrically measure hemoglobin and glucose. Moreover, no more than routine skill would have been required to use an alternative yet functionally equivalent reagents and techniques, since only the expected results would have been obtained; thus the use of alternative and functionally equivalent reagents and colorimetric methods would have been desirable to those of ordinary skill in the art based on the known ability to measure glucose and hemoglobin. Therefore, applicants arguments are not persuassive and the rejection is maintained.